k090228

510(k) SUMMARY
January 2009

APR 2 9 2009

Submitter: Alphatec Spine, Inc.
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Official Contact: Karla Schaffner, Regulatory Affairs Submissions Specialist

Trade/Model Name: ROC Lumbar Plating System

Common Name: Pedicle Screw Spinal System

Classification Regulation: MNI - 888.3070 - Orthosis, Spinal Pedicle Fixation
MNH - 888.3070 - Orthosis, Spondylolisthesis Spinal Fixation

Substantial Equivalence:

The ROC Lumbar Plating System is substantially equivalent in intended use and function to the following predicate devices.

Device Description:

The ROC Lumbar Plating System is a spinal fixation system that consisting of a variety of non-sterile, single use implants that facilitates the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development.

Intended Use

It is intended that this device, in any system configuration, be removed after development of solid fusion mass of spinal segments in skeletally mature patients. The ROC Lumbar Plating System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

Technological Characteristics Comparison:

The ROC Lumbar Plating System is equivalent to the referenced devices in that it is intended to be used to provide temporary internal lumbar fixation and stabilization during bone graft healing and/or fusion mass development. It is similar in terms of general design, intended use, and technological characteristics to the predicate devices.

Material composition is identical to numerous other Alphatec Spine products that have been cleared via the 510(k) process.

Nonclinical Performance Data:

Mechanical and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, *Spinal System 510(k)s - Guidance for Industry and FDA Staff*. This testing documented both static and fatigue performance characteristics. This testing clearly demonstrated that the performance characteristics satisfy the requirements of posterior lumbar fixation. As a result of this testing, the ROC Lumbar Plating System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc
% Karla Schaffner
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Carlsbad, CA 92008

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Re: K090228
Trade/Device Name: ROC Lumbar Plating System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: January 29, 2009
Received: January 30, 2009

Dear Ms. Schaffner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): ~~TBD~~ K090228

Device Name: ROC Lumbar Plating System

Indications for Use:

It is intended that this device, in any system configuration, be removed after development of solid fusion mass of spinal segments in skeletally mature patients. The ROC Lumbar Plating System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buenaventura

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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